No. 01-344

Supreme Court, U.S.
FILED
JAN 17 2002
CLERK

In the Supreme Court of the United States

TOMMY G. THOMPSON,
SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,

Petitioners,

v.

WESTERN STATES MEDICAL CENTER, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF THE INTERNATIONAL ACADEMY OF COMPOUNDING PHARMACISTS AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF THE *AMICUS CURIAE*[1]

Amicus curiae the International Academy of Compounding Pharmacists ("IACP") is an international non-profit association devoted to the protection and advancement of pharmaceutical compounding – one of the essential elements of the profession of pharmacy. The IACP's membership consists of more than 1400 pharmacists who engage in compounding, as well as approximately 200 other members, including physicians, patients, pharmacy students, and retired pharmacists. In defending the constitutionality of the limitations on speech relating to compounding, the government has asserted that the "introduction of compounded new drugs into interstate commerce" (Pet. Br. 18) was "unlawful in all circumstances" prior to 1997. According to the government, compounded drugs have been subject to a "generally applicable prohibition on [their] distribution" (*id.*) and "would be (and [are]) prohibited" (*id.* at 19) unless the statute at issue in this case is upheld. That position, if accepted, would devastate IACP's members in their practice of pharmacy and in their ability to serve patients' needs. The IACP thus has a critical interest in seeing that the Court be given an accurate picture of the law and history of pharmaceutical compounding. Moreover, IACP members regularly advertise. They thus have a strong interest in not being subjected to the unconstitutional limits on their speech imposed by the statute at issue in this case.

SUMMARY OF ARGUMENT

The government's defense of the limits on speech relating to pharmaceutical compounding rests on the suggestion that compounding was illegal from 1938, when the Federal Food, Drug, and Cosmetic Act was enacted, until 1997, when the statute at issue in this case was enacted. The government is simply wrong. Far from being illegal for 59 years, pharmaceuti-

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[1] Pursuant to this Court's Rule 37.3, letters from the parties consenting to the filing of this brief have been lodged with the Clerk of the Court. Counsel for *amicus curiae* wrote this brief in its entirety. No person or entity, other than the *amicus curiae*, its members, or its counsel, has made a monetary contribution to the preparation or submission of this brief.

cal compounding has long been an essential part of the practice of pharmacy – as ample historical evidence makes clear. Because compounding has always *been* legal, the government can have no interest, much less a substantial one, in saying that it can be *made* legal only if coupled with a restriction on advertising. The limits on speech concerning pharmaceutical compounding are unconstitutional.

ARGUMENT

I. Introduction

Under *Central Hudson Gas & Elec. Corp.* v. *Public Serv. Comm'n*, 447 U.S. 557 (1980), restrictions on commercial speech pass muster under the First Amendment if, and only if, the governmental interests underlying the restriction are "substantial"; the speech limitation "directly advances the governmental interest[s] asserted"; and the regulation is "not more extensive than is necessary to serve [the] interest[s]." *Id.* at 566; see Pet. App. 4a-5a. In arguing that Section 503A of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 353a,[2] is constitutional, the government says that the statute directly advances several interests "substantial" enough under *Central Hudson*: "preserv[ing] the effectiveness and integrity of the FDCA's new drug approval process" (Pet. Br. 19); "preserv[ing] the availability of compounded drugs" (*id.*); and "[a]chieving the proper balance between these two independently compelling but competing interests" (*id.* at 20).

But *Central Hudson* protects speech concerning only "lawful activity" (447 U.S. at 553), and here the government says that accurate advertising concerning compounded drugs relates to an activity that is "lawful" only because Congress has created a "carefully circumscribed exemption." Pet. Br. 18. In

[2] Section 503A of the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), Pub. L. No. 75-717, 52 Stat. 1040, was added by the Food and Drug Administration Modernization Act of 1997 ("FDAMA") Pub. L. No. 105-115, 111 Stat. 2296.

contrast, the government says, "[b]efore 1997," when FDAMA was signed into law, "the introduction of compounded new drugs into interstate commerce * * * was unlawful in all circumstances." *Id.* This means that but for the speech restrictions at issue in this case compounding "would be (and is) prohibited" (*id.* at 19); see also *id.* at 6 (maintaining that "[i]ntroduction of compounded drugs into interstate commerce without the approval of the FDA was thus illegal before enactment of FDAMA * * * and it remains illegal today unless the requirements in Section [503A] are satisfied") (citation omitted).

The implications of the government's view are breathtaking. The FDA has consistently taken the position that if drug *components* have moved through interstate commerce, the agency has jurisdiction over the product. See, *e.g.*, *United States* v. *Dianovin Pharm., Inc.*, 475 F.2d 100, 102-03 (1st Cir. 1973). At least one component of every compounded drug is invariably shipped in interstate commerce. Thus, under the government's theory, *all* extemporaneously compounded drugs would need to go through the rigorous new drug application ("NDA") process in order to be dispensed. The government's argument – if adopted – would effectively render all compounding without an NDA illegal, even if the product is dispensed intrastate.

But compounded drugs cannot comply with the NDA requirements. As enacted in 1938, the FDCA mandated that the sponsor of a "new drug" submit, among other things, "full reports of investigations which have been made to show whether or not such drug is safe for use." Pub. L. No. 75-717; FDCA § 505(b). (The Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (the "1962 Amendments") added the requirement that sponsors of new drugs demonstrate the efficacy of the drug as well.) Extemporaneously compounded drugs are

compounded drugs intended for use in a single patient, but conducting "investigations" with a single patient is impossible.[3]

Even if a pharmacist received several prescriptions for the same compounded drug, she could not possibly conduct clinical studies, submit the NDA, and await FDA approval in time to provide treatment for the patients. Furthermore, as the government notes, a separate FDA approval would be needed any time a physician's prescription called for even the slightest variation in the compounded drug, such as a different dose or route of administration. Pet. Br. 26. The preclusive effect of the NDA requirement is not merely a question of cost, as the government asserts, *id.*, but of the impossibility of conducting clinical studies and allowing the patient to receive promptly the medications prescribed by the physician. Even more astonishing, if the government is right that FDA approval is required for all compounded drugs, then on every occasion since 1938 that a pharmacist extemporaneously compounded a drug for a patient, the pharmacist was acting in violation of the FDCA – a statute that makes it a crime to violate the "new drug" provisions. FDCA § 301(d), 21 U.S.C. § 331(d); see FDCA § 303(a) (providing for imprisonment and/or fines for violations of § 301), 21 U.S.C. § 333(a).

The government, however, is wrong. Contrary to the government's suggestion that compounding was illegal until FDAMA created a limited "exemption" that allowed it, compounding is, and always has been, an essential and lawful part of the practice of pharmacy. In a rewriting of history reminiscent of the position it took in *Brown & Williamson* v. *FDA*, 529

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[3] FDA has repeatedly interpreted "investigations" to mean more than one clinical trial. In a guidance document drafted pre-FDAMA regarding clinical evidence of effectiveness (a requirement added in 1962), the agency asserted that "Congress generally intended to require at least two adequate and well-controlled studies * * * to establish effectiveness." GUIDANCE FOR INDUSTRY: PROVIDING CLINICAL EVIDENCE OF EFFECTIVENESS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS 3 (FDA 1998) (citing *Warner-Lambert Co.* v. *Heckler*, 787 F.2d 147 (3d Cir. 1986)).

U.S. 120 (2000), the government is asserting here that Congress banned compounding in the FDCA in 1938, then decided to permit it in FDAMA in 1997 subject to the limits on advertising. In point of fact, only recently did the FDA claim for the first time that agency approval of compounded drugs was required.[4]

As we explain below, the FDCA was not intended to, and did not, give the federal government the authority to regulate, much less ban, the practice of extemporaneous compounding. Rather, like the practice of medicine, regulation of the practice of pharmacy compounding was left by Congress to the states. Considerable historical evidence demonstrates that the FDCA was not intended to halt the practice of compounding; conversely, there is a complete lack of any historical or legislative evidence supporting the position staked out by the government.

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[4] The district court decisions in *United States* v. *Sene X Eleemosynary Corp.*, 479 F. Supp. 970 (S.D. Fla. 1979), aff'd, [1982-1983 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,207 (11th Cir. Jan. 12, 1983), and *Cedars North Towers Pharmacy, Inc.* v. *United States*, [1978-1979 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,200 (S.D. Fla. Aug. 28, 1978), do not support the government's argument that courts have held that compounding creates "new drugs." Pet. Br. 5-6. Both of these decisions involved "pharmacies" that were engaged in the wholesale manufacture of new drugs rather than drugs that were extemporaneously compounded, for individual patients. The circuit court decisions in *United States* v. *Algon Chem. Inc.*, 879 F.2d 1154 (3d Cir. 1989), and *United States* v. *9/1 Kg. Containers*, 854 F.2d 173 (7th Cir. 1988), are similarly inapposite. Pet. Br. 5-6. Both decisions involved the sale of bulk veterinary drugs, not extemporaneously compounded drugs for individual human patients. Finally, the government's citation of *Professionals & Patients for Customized Care* v. *Shalala*, 56 F.3d 592, 593 n.3 (5th Cir. 1995), for the proposition that compounding creates a "new drug" is incorrect. Pet. Br. 5. The referenced footnote merely notes that the FDCA does not expressly exempt pharmacies or compounded drugs from the new drug, adulteration or misbranding provisions. The legality of compounding was not squarely presented in that case, which involved a challenge to an FDA Compliance Policy Guide on procedural grounds and not the substantive interpretation of the FDCA as applied to compounding. To the extent that the footnote suggests that compounding creates "new drugs" under the FDCA, it is incorrect.

II. Historical Evidence Belies the Government's Suggestion that Compounding Was Illegal Prior to FDAMA

A. *Compounding Has Always Been an Accepted Part of the Practice of Pharmacy*

Remington's Practice of Pharmacy – often described as the "Bible" of pharmacy practice, and relied on widely in colleges of pharmacy both historically and today – stated in 1936 that "[p]harmacy is the science which treats of medicinal substances. It embraces not only a knowledge of medicines and the art of preparing and dispensing them, but also their identification, selection, preservation, combination, analysis and standardization* * *. *Compounding* consists of the skilful blending of two or more ingredients." REMINGTON'S PRACTICE OF PHARMACY 1 (8th ed. 1936) (emphasis in original). Compounding has been part of the practice of pharmacy since its inception. An Egyptian papyrus scroll dating from the 16th century B.C. discussed the compounding of medicines. *Id.* at 3-4. In this country, John Winthrop, Jr. (1606-1676), son of the first governor of Massachusetts, was one of the first Americans to practice pharmaceutical compounding. REMINGTON'S PRACTICE OF PHARMACY 13 (12th ed. 1961). The United States Pharmacopoeia – an official compendium of drug information recognized as authoritative by the FDCA – has included instructions on compounding medications since 1820. *History and Background Information on USP's Activities in Compounding Pharmacy Practices*, 27 PHARMACOPEIAL F. 3169 (2001).

In 1938, when the FDCA was enacted, pharmacy compounding was ubiquitous. Pharmacists compounded more than 250 million prescriptions annually. *Proceedings of the Local Branches*, 14 J. AM. PHARM. ASS'N 232, 233 (1935). In addition, the pharmacy laws of every state defined the practice of pharmacy to include compounding. *Joint Session of the American Pharmaceutical Association, the American Association of Colleges of Pharmacy and the National Association of Boards of Pharmacy*, 17 J. AM. PHARM. ASS'N 1000, 1010-13 (1938). For example, New York's pharmacy act defined

"pharmacy" to mean a place in which "drugs, chemicals, medications, prescriptions, or poisons are compounded." REMINGTON'S PRACTICE OF PHARMACY 1352 (8th ed. 1936); see also O'CONNELL & PETTIT, A MANUAL OF PHARMACEUTICAL LAW 159 (1938) (Pennsylvania law defined "pharmacy" similarly). The New Jersey Board of Pharmacy promulgated regulations providing that pharmacy interns were required to compound personally at least 600 prescriptions during their internship in order to be licensed. *Id.* at 23 n.1.

B. *Pharmacists Supported the Passage of the FDCA*

In the years immediately preceding the passage of the FDCA, the American Pharmaceutical Association ("APhA"), the first professional association of pharmacists, strongly supported passage of the FDCA. APhA supported the legislation because of concerns that manufactured proprietary and patent medications were largely unregulated under the Federal Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768. Pharmacists were apprehensive about the quality of manufactured products, as well as the manufacturers' advertising practices. In a 1936 article, Robert P. Fischelis, the President of APhA, remarked:

> We see the actual compounding of medicines taken over by large manufacturing units and the reduction of the average retail pharmacist to a dispenser of ready-made medicines.
>
> Without adequate control over advertising and production of their remedies, the public is being educated by manufacturers to medicate itself, and the use of possibly harmful drugs, without medical or pharmacal [sic] advice, is being encouraged to the point where public health demands some type of supervision. Passage of a revised Federal Food and Drug Law giving the U.S. Food and Drug Administration control over advertising [of manufactured drugs], requiring the disclosure of the formulae of proprietary remedies and strengthening the public control over the drug industry, is

> essential to the public welfare and should be forthcoming at this session of Congress.

Golden Anniversary Address, 15 J. AM. PHARM. ASS'N 476, 476 (1936). In a 1935 editorial, Fischelis wrote:

> It is difficult to understand why [opponents of the FDCA], whose chief interest in food and drug legislation is to block efforts to compel truthful labeling and advertising of foods and drugs and to ease the path of fakers in the food and drug industries, should be in a position to thwart the efforts of earnest legislators and respectable citizens in providing proper control of the manufacture and distribution of drug products.

Federal Drug Legislation Must Not Be Permitted to Die, 14 J. AM. PHARM. ASS'N 349, 349 (1935). From the pharmacists' perspective, passage of the FDCA was necessary to control *manufacturers*.

> It seemed monstrous to us that the retail pharmacist must meet a high educational standard, must satisfy exacting State Board requirements and must subject himself to almost continuous regulation and control, while the manufacturer, even though his products are much more widespread in distribution, is required by law to meet no standard whatsoever. In other words, while exacting requirements were thrown around the man who would compound a prescription for a dozen pills, there was no such restriction surrounding the man who might produce these same pills by the ton.

Swain, *Legislative Weather-Vanes*, 15 J. AM. PHARM. ASS'N 794, 796 (1936).

There is no historical evidence that pharmacists believed that the FDCA encompassed extemporaneous pharmacy compounding. Pharmacists were not alone. There is no contemporaneous evidence that anyone – including the FDA –

thought the FDCA would prohibit pharmacy compounding, one of the basic forms of health care in the United States.

C. *The Legislative History of the FDCA Demonstrates the Acceptance of the Practice of Compounding*

Little was stated in the legislative history of the FDCA about the meaning of section 505(a), 21 U.S.C. § 355(a), which prohibited "new drugs" from being introduced into interstate commerce unless they have been approved by the federal government. However, the legislative history does suggest that section 505 was intended to apply solely to manufacturers of new drugs, and was not designed to affect the actions of physicians and pharmacists in fulfilling their professional responsibilities. In fact, physicians, as well as pharmacists, were permitted to compound medicines as part of their practice: "About the only real privilege granted to pharmacists under the pharmacy laws was that of compounding physicians' prescriptions, and this was no exclusive privilege as the pharmacist shared this right with the physician himself." Swain, *supra,* at 795.[5]

The subject of pharmacists arose in the debate on S. 5, the bill that became the FDCA, prior to the addition of section 505. The discussion did not directly address drug compounding by pharmacists, but centered on a provision which stated that "No drug defined in an official compendium shall be deemed to be adulterated * * * because it differs from the standard of strength, quality, or purity therefor set forth in an official compendium, if its standard of strength, quality, or purity be plainly stated on its label." 81 CONG. REC. 2001, 2014 (1937).

Senator Copeland observed that if a physician in New Jersey wanted to prescribe Fowler's solution of arsenic in the

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[5] Physicians continue to compound. See, *e.g.*, Ark. Code Ann. § 17-92-102 (authorizing physicians to compound their own prescriptions). Although state legislatures repeatedly enacted laws permitting physician compounding after 1938, under the government's analysis, all physician compounding was also outlawed that year.

standard strength, he simply had to write "Fowler's solution, U.S.P." on the prescription, and he "may depend upon the ethical standards of the pharmacist filling that prescription that when it is filled it will be * * * 'Fowler's solution, U.S.P.'" *Id.* at 2017. Senator Moore responded:

> That may * * * be true enough. He might also write that on his prescription, and he might also tell the druggist how he wishes him to prepare it. However, that does not alter the fact that the bill provides that no drug below the standard represented by the pharmacopoeia and the other standards is adulterated if on the container the adulteration is made manifest.

Id. This exchange exemplified an awareness that physicians relied on pharmacists to "prepare," *i.e.*, compound, drugs for their patients in accordance with instructions set forth in prescriptions. Such preparation included the compounding of drugs.

That section 505 was targeted toward drug manufacturers, and not physicians and pharmacists, is emphasized in remarks by Representative Coffee which appeared in the June 1, 1938 *Congressional Record*. Representative Coffee argued that S. 5 offered inadequate protection against the type of tragedy that had occurred with the marketing of a new and untested drug, elixir of sulfanilamide, in 1937. 83 CONG. REC. 2279 (app.) (1938). He commented that at the time of the tragedy, Secretary of Agriculture Henry Wallace "made excellent recommendations as to the minimum requirements of legislation which should be enacted to prevent the public thus becoming prey of *criminally careless or ignorant manufacturers*." *Id.* (emphasis added).

In Representative Coffee's view, the proposed section 505, which required the "licensing" of new drugs, failed to incorporate all the provisions believed by Secretary Wallace to be essential. Summarizing Secretary Wallace's and his own concerns, Representative Coffee said:

> Secretary Wallace stated the case for licensing the manufacturers of potentially harmful drugs briefly and well: "In the interest of safety, society had required *that physicians be licensed to practice the healing art. Pharmacists are licensed to compound and dispense drugs*. Electricians, plumbers, and steam engineers pursue their respective trades under license. But there is no such control *to prevent incompetent drug manufacturers from marketing any kind of lethal poison*."

Id. (emphases added). Thus, section 505 of the FDCA was not intended to affect the professional activities of physicians or pharmacists, including their practice of compounding, but to control drug manufacturers. There is no indication whatsoever that Congress intended to ban compounding, which played an irreplaceable role in the health care system. If compounding had been banned in 1938, as the government argues more than sixty years later, the results would have been catastrophic, since there were, in many cases, no alternatives to compounded medications. In 1938, the practice of medicine without compounding was inconceivable.

D. *The Actions of the Federal Government and Members of the Pharmacy Profession, As Well As Official Compendia, Make Clear That Compounding Was Not Regulated by the FDCA*

Considerable historical evidence from the period immediately following the enactment of the FDCA rebuts the government's contention that the statute banned extemporaneous compounding by pharmacists. For example, in a series of articles by United States military and civil service pharmacists, the federal government recognized the importance of compounding as part of the practice of pharmacy in the armed forces and the civil service. See Smith, *Training Army Pharmacy Technicians*, 1940 J. AM. PHARM. ASS'N 296, 297 ("The pharmacy technician has five chief functions * * * (3) routine dispensing and compounding of medications for wards and clinics of the hospital; (4) compounding of prescriptions for

hospital and out-patients * * * ."); Schwartz, *Pharmacy in the U.S. Navy*, 1940 J. AM. PHARM. ASS'N 299, 299 ("Every naval unit to which a medical officer is attached has a fully equipped pharmacy. It has * * * all the paraphernalia required in compounding and dispensing medicine."); Ernest, *Pharmacists in the Civil Service*, 1940 J. AM. PHARM. ASS'N 301, 301 ("Where drugs or medicines are dispensed or doctors' prescriptions are compounded, a duly qualified registered pharmacist is found to be employed."). There is no indication in these discussions that compounding results in a new drug that must be approved by FDA, or that federal employees were being advised to break the law. Rather, compounding is discussed in the articles by federal government officials as an accepted part of the practice of pharmacy, rather than, as now asserted by the government, a crime.

Moreover, both the United States Pharmacopoeia ("USP") and the National Formulary ("NF") recognized the practice of compounding and included instructions for compounding numerous drugs as part of their compendial standards. See, *e.g.*, U.S.P. XII, at 364-65 (1942) (instructions for compounding pills of ferrous carbonate); *id.* at 446-48 (suppositories); *id.* at 505-06 (tinctures); *id.* at 532-41 (ointments); N.F. VII, at 400-01 (1942) (syrups); *id.* at 439-40 (tinctures); *id.* at 469-77 (ointments).

The inclusion of compounding formulas in the USP and NF is strong evidence that compounding was widely recognized as legal. Congress identified both the USP and NF as "official compendia" in the FDCA. FDCA § 201(j); 21 U.S.C. § 321(j). Any product or compounded preparation listed in a monograph in the USP or the NF must therefore comply with the compendial standards or they are deemed adulterated and misbranded. FDCA §§ 501(b) (adulteration), 502(g) (misbranding), 21 U.S.C. §§ 351(b), 352(g). These compendia are the only statutorily recognized compendia in the FDCA. Indeed, the importance of the USP was such that numerous federal government health officials, including representatives from the FDA, the medical departments of the Army and Navy, the U.S. Public

Health Service, and the Department of Commerce, were delegates to the U.S. Pharmacopeial Convention of 1940. U.S.P. XII, at lix. Just two years after the enactment of the FDCA, this USP Convention adopted monographs for many compounded drugs.

Similarly, the pharmacy profession clearly understood that the FDCA did not ban compounding. First, APhA celebrated the enactment of the FDCA, stating in a 1938 article that:

> It is gratifying to be able to note the enactment of the new Food, Drug and Cosmetic Legislation by the Federal government, to supplant the outmoded statute of 1906 * * * . We believe, despite the opposition encountered, that a greatly improved piece of legislation has been enacted, and that it is going to bring about a more wholesome condition in the field of manufactured medicinal products.

Abstract of the Proceedings of the House of Delegates, APhA, 17 J. AM. PHARM. ASS'N 1052, 1055 (1938). Second, following the passage of the FDCA, APhA supported state pharmacy legislation to complement the federal act. APhA proposed model legislation that stated that the "term 'pharmacy' * * * shall be held to mean and include every store or shop or other place * * * where physicians' prescriptions are compounded * * * ." *Joint Session of the American Pharmaceutical Association*, *supra*, 17 J. AM. PHARM. ASS'N at 1013. Under the government's novel theory, this legislation defined pharmacy in terms of an illegal act. Further, in an article entitled *Jurisprudence in the Pharmaceutical Curriculum*, an officer of the APhA noted that:

> Everyone with any familiarity at all with the field knows that, while *the Federal Food, Drug and Cosmetic Act has only an indirect relation to the pharmacist engaged in the operation of a retail drug store* within a given area of any given state, also knows that this same pharmacist is held to a strict observance of another federal law; namely, the Harrison Narcotic Act [predecessor to the Controlled

> Substances Act, see *infra* at 17.]. The mere fact that one act of Congress imposes a heavy burden upon the pharmacist, *while another Congressional act is only of incidental importance to him*, should, at least, stimulate his curiosity.

1940 J. AM. PHARM. ASS'N 273, 273 (emphases added).

Just as there is no evidence that pharmacists believed that one of their primary functions had been outlawed by the FDCA, there is no evidence that FDA ever asserted that the FDCA regulated compounded drugs as new drugs. Indeed, in an article in the *APhA Journal* addressed to pharmacists, a former senior FDA drug official discussed the "new drug" provision of the FDCA without any mention that it affected the practice of compounding. See Klumpp, *The Philosophy of the Food, Drug and Cosmetic Act*, 1941 J. AM. PHARM. ASS'N 379, 381 (written by the former Chief of the Drug Division of the FDA).

E. *Post-Enactment Historical Evidence Supports the Proposition that Compounding Was Not Governed by the FDCA*

The historical evidence from the years that followed the enactment of the FDCA demonstrates that compounding remained an integral part of health care. No one asserted that compounding was made illegal by the FDCA, while every state affirmatively authorized the compounding of drugs. "In mentioning rights of pharmacists, state statutes generally list the following as rights: to practice pharmacy, * * * to compound prescriptions * * * ." PETTIT, MANUAL OF PHARMACEUTICAL LAW 26 (3d ed. 1962). The 1951 edition of *Remington's Practice of Pharmacy* included a discussion of the FDCA without any mention of compounding being regulated under the Act. It also noted that compounding was both permitted and regulated by the states. REMINGTON'S PRACTICE OF PHARMACY 1163 (10th ed. 1951) ("The practice of pharmacy * * * is regulated by law in every state. The police power, in the basic governmental sense, is invoked to surround the compounding and dispensing of prescriptions."); *id.* at 1173-77 (discussion of FDCA, no mention of compounding); *id.* at 1195-97 (discussion

of minimum equipment needed for compounding and prescription department); *id.* at 1220 (discussion of the prescription, noting that the inscription section of the prescription "contains the names and quantities of the ingredients" used to compound); *id.* at 1227-28 (discussion of the filling and compounding of the prescription); see also REMINGTON'S PRACTICE OF PHARMACY 1567 (12th ed. 1961) (inscription of prescription contains "names and quantities of the prescribed ingredients"); *id.* at 1571 (discussion of the compounding of the prescription); *id.* at 1697 (stating that "[t]he regulation of the practice of pharmacy is a function of the states, and not of the Federal Government"); *id.* at 1706-10 (analysis of FDCA, no mention of compounding). A later edition of *Remington's* made the same point quite plainly: "The regulation of the practice of pharmacy is a function of the states, and not of the Federal Government." REMINGTON'S PHARMACEUTICAL SCIENCES 1963 (14th ed. 1970); see *id.* at 1976-85 (treatment of FDCA, no mention of compounding).

Other pharmacy texts similarly referred to drug compounding as a universally accepted practice regulated by the states. For example, the preface to *Husa's Pharmaceutical Dispensing* – another important pharmacy treatise dealing almost exclusively with compounding – states that "[c]ompounding of medicinal products will always be an important function of the pharmacist in spite of the fact that practically all prescriptions now call for prefabricated medication." HUSA'S PHARMACEUTICAL DISPENSING 36-42 (6th ed. 1966) (discussion of federal and state laws regarding pharmacy; noting that regulation of practice of pharmacy, including "licensure and standards for compounding and dispensing of prescriptions, is embodied in the laws of the various states"). More recent pharmaceutical texts have also discussed the importance of compounding, without noting any federal regulation of the practice. See DISPENSING OF MEDICATION ch. 12 (9th ed. 1984) (chapter on extemporaneously compounded formulations). The authors of the chapter entitled "Extemporaneous formulations" stated that "[t]he purpose of prescription compounding is to dispense safe, effective medication pursuant to the order of a duly licensed practitioner whose

judgment has dictated that individualized drug therapy is required for a patient." *Id.* at 258. The premise underlying this book is that compounding is legal.

While the authors of these widely utilized pharmacy texts clearly understood the importance of the FDCA in regulating the manufacture of drugs, no author even suggested that the FDCA rendered compounded drugs illegal unless approved by the federal government. Indeed, the various treatises from the period are uniform in recognizing that *state* governments – through the state legislatures and state boards of pharmacy – both permitted and regulated compounding.

The government's theory is further belied by the fact that pharmacy students took classes in compounding. For example, a report prepared by the American Association of Colleges of Pharmacy discussed the importance of pharmaceutical compounding as part of the pharmaceutical curriculum. See THE PHARMACEUTICAL CURRICULUM 144-45, 148-49 (1952) (discussing the centrality of compounding courses in colleges of pharmacy). Many states also required practical experience in compounding and dispensing prescriptions prior to licensure. PETTIT, MANUAL OF PHARMACEUTICAL LAW 25-26 (3d ed. 1962). For example, the California Board of Pharmacy required 950 hours of practical experience in the compounding and dispensing of prescriptions. *Id.* at 26. The government's novel contention is that colleges of pharmacy throughout the country were teaching their students about an illegal practice, and that the states were requiring pharmacists to display proficiency in an illegal act to be licensed.

The 1962 Amendments further demonstrate that extemporaneous compounding by pharmacists was not precluded by the FDCA. The 1962 Amendments added provisions to the FDCA, among other things, requiring manufacturers to register with the FDA and list their drugs. See FDCA § 510(b), 21 U.S.C. § 360(b). Pharmacies were (and still are) exempt from these requirements. See FDCA § 510(g)(1) (exempting pharmacies from registration and listing), 21 U.S.C. § 360(g)(1). Pharmacies

were also subject to more limited inspections than manufacturers. FDCA § 704(a)(2)(A), 21 U.S.C. § 374(a)(2)(A). It would make no sense to exempt pharmacies from the relatively trivial paperwork requirements of filing registration and listing forms, were it necessary to comply with the onerous requirements of demonstrating safety and effectiveness of each compounded drug in an NDA. The government's illogical theory is that the 1962 Amendments required pharmacists to prove efficacy through controlled clinical studies for every compounded drug, an impossible task for a drug administered to a single patient, but were exempt from the ministerial task of filing a one-page form to list the drug.

Additional evidence that Congress did not intend the FDCA to govern pharmacy compounding is found in the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 ("CSA"). In the CSA, Congress defined the term "manufacture" to exclude:

> the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice.

CSA § 102(14), 21 U.S.C. § 802(15). Although there is little discussion of this exemption in the legislative history, it is implausible that Congress would have exempted compounding from regulation under the CSA if the act of compounding without an NDA were illegal under the FDCA. On the contrary, the only explanation is that Congress, in permitting the compounding of controlled substances, did not believe that the FDCA had already banned extemporaneous compounding.

F. *In the Years Immediately Prior to Enactment of FDAMA, Compounding Was Widely Recognized as Legal*

In the years prior to the enactment of FDAMA, two prominent organizations – both of which were given a role by Congress in the regulation of compounding – adopted standards

regulating compounding. By establishing standards for compounding, these organizations both affirmed the legality of compounding. In 1993, the National Association of Boards of Pharmacy ("NABP") – the professional organization whose members are the state boards of pharmacy – adopted Good Compounding Practices as part of their Model State Pharmacy Act. See NABP MODEL STATE PHARMACY ACT app. C.1 (Good Compounding Practices Applicable to State Licensed Pharmacies). These guidelines, adopted in whole or in part by numerous states, set forth minimum standards for the practice of compounding. The standards include detailed instructions regarding equipment, adequate space for compounding, the training and qualifications of personnel involved in compounding, storage of raw materials, and drug compounding controls. In 1996, USP – one of the two official compendia mentioned in the FDCA – stated that "[c]ompounding is an integral part of pharmacy practice and is essential to the provision of health care." USP/NF Supplements 3531 (1996). At that time, USP adopted a monograph setting forth standards for compounding. See *id.* (Chapter <1161> Pharmacy Compounding Practices). The monograph includes standards regarding equipment, facilities, ingredient sources, stability criteria, acceptable compounded dosage forms, record retention, and quality control. Neither the NABP's Good Compounding Practices nor the USP's monograph states that NDAs are required for compounded drugs.

Thus, the two standard-setting organizations identified by Congress in section 503A of FDAMA, 21 U.S.C. § 353a, established compounding guidelines before 503A was enacted. These actions further controvert the government's claim that prior to FDAMA, all compounding resulted in the creation of an illegal new drug.[6]

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[6] Significantly, both USP and NABP were given roles to play regarding compounding under FDAMA. Congress directed the Secretary of Health and Human Services to consult with NABP in developing a memorandum of understanding for use with the states in regulating the interstate distribution of compounded drugs. FDCA § 503A(b)(3)(B), 21 U.S.C. § 353a(b)(3)(B).

At the same time these standards were developed, even agencies of the federal government continued to promote the practice of compounding. For example, the Department of Defense stated in its policy on pharmacies at military treatment facilities that "[t]he pharmacy may bulk compound pharmaceutical preparations using formulas from official compendiums, other references, or a locally developed formula." Memorandum for Ass't Secretaries of the Army, Navy & Air Force from Ass't Sec'y of Defense re: Tri-Service Pharmacy Policy Guidance (Jul. 26, 1995), *available at* http://www.tricare.osd.mil/policy/fy95/pharmpol.html. The Veterans Health Administration ("VHA") similarly required all VHA pharmacies to set aside sufficient space for extemporaneous compounding. VETERANS HEALTH ADMINISTRATION – PHARMACY SERVICE, VA HANDBOOK 7610, ch. 268, at 268-4 (Jan. 11, 1990), *available at* http://www.va.gov/facmgt/ standard/space_idx.asp.

Moreover, in the years leading up to FDAMA, state legislatures continued to authorize compounding. Congress recognized this fact in the legislative history to FDAMA, stating that "[a]ll States include[d] compounding as a core component of the profession of pharmacy." S. REP. NO. 105-43, at 67 (1997); see also Underhill, *Regulatory and Clinical Aspects of the Resurgence of Compounding by Pharmacists*, 22 DRUG. DEV. & INDUS. PHARMACY 659, 660 (1996) ("Traditionally, compounding by pharmacists of a prescription * * * for a patient has been under the control of the relevant State Board of Pharmacy and in fact 41 of the 50 state laws which define the practice of pharmacy specifically including [sic] 'compounding' per se in their definition"). The government's assertion about the illegality of compounding would nullify the pharmacy laws of all 50 states, for each state explicitly authorized compounding. Indeed, not only did all state legislatures authorize pharmacy compounding, but several state boards of pharmacy also defined

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Representatives from NABP and USP were to participate in an advisory committee prior to the issuance of regulations implementing section 503A. FDCA § 503A(d), 21 U.S.C. § 353a(d).

"unprofessional conduct of a pharmacist" to include refusing to compound prescriptions.[7] Refusing to compound prescriptions can therefore result in professional discipline by states that require pharmacists to compound.

In the years preceding the enactment of FDAMA, compounding pharmacies differed to an extent in their practices. Most pharmacies engaged in limited extemporaneous compounding to meet the needs of local patients. Other pharmacies began to specialize, and fill prescriptions from a more geographically diverse area. With the growing importance of intravenous admixtures, hospital pharmacies performed increasing amounts of compounding. Regardless of their setting or the geographic area served by these pharmacies, they shared common traits: licensure by state boards of pharmacy, compounding prescriptions pursuant to state legislation explicitly authorizing the practice, and dispensing medications to their patients to fill prescriptions by physicians. They also shared another trait – under the government's contention, all of their compounding was illegal.

Immediately preceding the enactment of FDAMA, standard-setting organizations, federal government agencies and the state boards of pharmacy all permitted compounding when performed in compliance with state regulation. Under the government's revisionist approach, the Department of Defense, the Veterans Health Administration, the state legislatures, the state boards of pharmacy, the U.S. Pharmacopoeia, and the National Association of Boards of Pharmacy were all advocating that pharmacists commit criminal acts.

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[7] Mass. Regs. Code tit. 247, § 9.01(16); N.D. Admin. Code § 61-04-04-01(14); Minn. R. 6800.2250; see also NABP MODEL STATE PHARMACY ACT, MODEL RULES FOR PHARMACEUTICAL CARE § 5(2) ("Unprofessional conduct shall include * * * [u]nreasonably refusing to Compound or Dispense Prescription Drug Orders that may be expected to be Compounded or Dispensed in Pharmacies by Pharmacists.").

In sum, the government's claim that compounding was illegal prior to the enactment of FDAMA turns history on its head. Between 1938 and 1997, pharmacists dispensed billions of compounded. In 1995, pharmacists compounded approximately 220 million prescriptions. *Pharmaceutical Care: Part of TQM?*, DRUG TOPICS 10 (July 10, 1995). Over 96% of hospitals surveyed by the American Society of Hospital Pharmacists in 1991 engaged in extemporaneous compounding of sterile drug products. *National Survey of Quality Assurance Activities for Pharmacy-Prepared Sterile Products in Hospitals*, 48 AMER. J. OF HOSP. PHARM. 2398, 2401 (1991). Under the government's theory, each drug that was dispensed represented a criminal act. Because compounded prescription drugs cannot be dispensed without a prescription, each of these violations was facilitated by a physician or other authorized prescriber. Aiding and abetting these innumerable violations were the colleges of pharmacy that taught the practice of compounding, the state legislatures that authorized compounding, the state boards of pharmacy that regulated compounding and required pharmacists to maintain compounding equipment, the National Association of Boards of Pharmacy and the USP and other compendia that set forth compounding standards and compounding instructions. Contrary to the government's assertion, Pet. Br. 25, these activities did not occur because Congress had prohibited compounding in 1938 but FDA had silently exercised its enforcement discretion. Rather, they occurred because Congress, in enacting the FDCA, did not outlaw extemporaneous compounding.

G. *The Legislative History of FDAMA Supports the Proposition that Compounding Was Not Regulated by the FDCA*

The legislative history of FDAMA itself shows Congress recognized that compounding was a state-authorized and regulated activity. A Senate Committee Report confirms that "[s]tates currently have the authority to license pharmacists and regulate pharmacies, including the scope of pharmacy practice. All States include compounding as a core component of the profession of pharmacy." S. REP. NO. 105-43, at 67. The fact

that Congress itself recognized that compounding was defined by the states as a "core component" of the practice of pharmacy further demonstrates that compounding was not banned by the FDCA as the government asserts.

III. This Court's Commercial Speech Doctrine Protects Advertising for Legal Activities Such as Pharmacy Compounding

In light of the overwhelming evidence demonstrating that compounding has been legal all along, and not just since the passage of FDAMA, the ban on advertising contained in Section 503A cannot possibly satisfy *Central Hudson*, 447 U.S. at 566.

The government asserts that the limits on speech are needed to "preserve the effectiveness and integrity of the FDCA's new drug approval process." Pet. Br. 19; see *id.* at 33, 37-38. The government posits that compounding pharmacies evade the onerous NDA requirements of section 505(a) of the FDCA, while engaging in the advertisement of new drugs and that this is inequitable to manufacturers, which must comply with section 505(a). The government further speculates that this may encourage others to evade the new drug requirements through compounding rather than filing an NDA.

But compounded drugs are *not subject* to the NDA process and never have been. Compounding pharmacies are not, therefore, evading the requirements of the FDCA (or encouraging others to do so by example), and a ban on advertising compounded drugs cannot "directly advance," or advance at all, the government's interest in NDAs.

The government further argues that Section 503A is necessary lest physicians, spurred by compounding pharmacies' advertisements, otherwise prescribe vast quantities of compounded drugs, rather than commercially available pharmaceutical products. The Court has previously rejected similar arguments. In *Virginia State Bd. of Pharmacy* v. *Virginia Citizens Consumer Council*, 425 U.S. 748, 767 n.21 (1976), the Court rejected arguments that advertisements of low drug prices could

lead to overconsumption, stating that "[b]y definition, the drugs at issue here may be sold only on a physician's prescription. We do not assume * * * that simply because low prices will be freely advertised, physicians will overprescribe, or that pharmacists will ignore the prescription requirement." Likewise, alerting physicians to the availability of specific compounded products will not lead to overprescribing by physicians since the compounded drug will be prescribed only where a medical need exists. The government's argument that the advertising restriction is necessary to preserve a "careful balance" between making compounded drugs available and preventing too much compounding is not directly advanced by the advertising restrictions at issue.

Contrary to the government's arguments, there is considerable value to allowing compounding pharmacies to inform the public about which products they can compound. Many pharmacies specialize in compounding certain types of products, such as respiratory drugs or hormone replacement therapy, yet under FDAMA, pharmacists are not even allowed to advertise the class of drugs that they can compound. If a pharmacist cannot inform a physician of the types of drugs that he is capable of compounding, the physician will not be aware of what options may be available. While manufactured drugs are usually appropriate today, they do not always meet a patient's needs. Compounding is particularly useful for patients who are allergic to dyes, flavors or other excipients. Additionally, compounding is often used to create pain medications for patients who cannot swallow pills, or for patients for whom the standard dosage forms are inappropriate.[8] According to the government, the only appropriate advertisement under FDAMA is that a pharmacy is capable of compounding. This bare assertion of capability does not inform the physician of the types of drugs that a pharmacy can tailor to meet an individual patient's needs pursuant to a physician's instructions.

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[8] *Amicus Curiae* American Pharmaceutical Association discusses this issue at length.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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JANUARY 2002